



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------------------------|-------------|----------------------|--------------------------|------------------|
| 10/633,350 | 08/01/2003 | Jude A. Kral | ST8724US | 3716 |
| 22203 | 7590 | 06/02/2006 | EXAMINER | |
| KUSNER & JAFFE HIGHLAND PLACE SUITE 310 6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143 | | | JASTRZAB, KRISANNE MARIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1744 | |

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,350

Applicant(s)

KRAL ET AL.

Examiner

Krisanne Jastrzab

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al., U.S. patent No. 5,761,069 in view of the combination of Mapson et al., U.S. patent No. 6,485,684, Malkin et al., U.S. patent publication 2004/0091387 A1 and Moser, U.S. patent No. 5,279,799.

Weber et al. teach a system for monitoring fluid circulation in a reprocessor apparatus for sterilization (Abstract, column 1 lines 7-9) where there are fluid connections (column 14 lines 57-60). The monitoring system comprises a pressure sensor for sensing a pressure and generating an electrical signal indicative of a sensed pressure (column 12 lines 24-31), and a controller (column 4 lines 55-57) responsive to the electrical signal (column 12 lines 30-31). Weber et al. teach the pressure sensed is indicative of the failed circulation pump (column 12 lines 26-29), however, Weber et al. fail to teach the importance of ensuring the connections within the reprocessing system are secure.

In U.S. Patent 6,485,684, Mapson et al. teach a reprocessing system for endoscope sterilization in which the exterior surfaces of endoscopes are sprayed with sterilant and the inner lumens are pressurized with sterilant through connected tubing (Abstract). Instruments such as endoscopes have a plurality of openings, and require that sterilant is flowed through different openings at different pressures. Additionally,

some lumens do not need to be sterilized and would be damaged when contacted by fluids (column 1 lines 29-40). When improper connections are made between sterilant tubes and medical instruments, assurance that the sterilant is contacting all microorganisms in the lumens is lost (column 1 lines 49-52), leaving the instrument contaminated. Mapson et al. also teach using a leak detector in the reprocessing system to determine if the lumen is holding a preselected vacuum or positive pressure (column 4 lines 24-27). This shows the importance of having a fully pressurized system to expose all microorganisms to sterilant and ensuring certain parts of instruments are not contacted by fluids. A decrease in fluid pressure within the system would be evidenced by an improper connection.

In U.S. Patent Application Publication 2004/0091389 A1, Malkin et al. teach that in a flexible endoscope steam sterilization system, pressure tests can be run to determine the channels or lumens that are connected with the steam sterilant source (paragraph 48).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pressure sensor in Weber et al.'s invention to determine if there is an improper connection between the medical instrument and the sterilant ports because an improper connection would lead to fluid pressure and sterilant losses, thereby increasing the expense to operate Weber et al.'s reprocessor apparatus. Additionally, a proper connection would have been beneficial to Weber et al.'s reprocessor because it would have further ensured that medical instrument sterilization was complete by leaving no part of the instrument contaminated as taught

by Mapson et al. above, which is a concern since Malkin et al. teach the complexity of the inner parts of endoscopes (paragraph 8).

In U.S. Patent 5,279,799, Moser et al. teach a sterilization system for endoscopes in which endoscope ducts are checked for clogs. When a clogged duct is determined, the specific duct is indicated on a display field of the control unit (column 6 lines 15-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to display the location of an improper connection found in Weber et al.'s reprocessor apparatus on the screen display just as the clogged duct location was displayed in Moser's invention to notify the user of which connection is improper so the connection can be made proper, thereby increasing the response time for operators to make the reprocessor safe from spilled sterilant. This would have also aided in preventing the shutdown of all the reprocessors at once to correct the connection, since Weber et al. teach that all four reprocessors could be controlled and monitored simultaneously (column 8 lines 22-26).

Regarding claim 3, Malkin et al. further teach that the central processor responds with error messages, status notifications, and the like at the user interface display (paragraph 80). It would have been obvious to one having ordinary skill in the art at the time the invention was made to display corrective actions on the display screen of Weber et al.'s invention to aid hospital users who are new to using the reprocessor apparatus in correcting a connection problem, which, as Malkin et al. teaches, would contribute to faster-acting sterilization (paragraph 11).

Regarding claim 4, Weber et al. teach displaying information associated with the type of medical instruments being reprocessed (column 5 lines 7-10, column 9 line 61-column 10 line 9).

Regarding claim 5, Weber et al. teach the controller workstation comprises a keyboard (column 6 lines 26-28).

Regarding claim 6, Weber et al. additionally teach the input unit allows input of information for selecting the type of device being sterilized (column 5 line 66-column 6 line 6). Inserting a diskette and inputting information into the keyboard will allow the user to select the reprocessing unit to use based on the device being sterilized (column 7 line 62-column 8 line 31).

Regarding claim 7, Weber et al. in view of Malkin et al. teach the controller would determine the connection of medical instruments to sterilant sources as described above. Moser discloses that a leaking endoscope will result in a pressure drop and that an endoscope with no leaks will increase pressure (column 5 lines 34-49), making a leak intrinsic to an improper connection because the pressure sensors are connected to the line entering the endoscope (column 5 lines 18-23). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to conclude that a proper connection is obtained when the pressure increased in the medical instrument. Moser also teaches a predetermined pressure of 0.20 bar is reached and the controller makes the appropriate pressure reductions (column 5 lines 34-38).

Regarding claim 8, Moser teaches an alarm is triggered when there is a leak in the endoscope (column 5 lines 49-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to implement an audible alarm so that users that were not looking directly at the screen or working on other operations in the control room could be notified promptly, eliminating the consequence of being alerted too late and endangering personnel with leaking sterilant.

Regarding claim 9, Moser teaches that a pressure value associated with an improper connection is lower than 0.18 bar and a pressure higher than 0.18 bar is associated with a proper connection (column 5 lines 34-49).

Response to Arguments

Applicant's arguments filed 3/13/2006 have been fully considered but they are not persuasive. Applicant argues that the combination set forth would not properly provide display means indicating the location of the improper connection, however, the Examiner would disagree. Moser clearly teaches providing indication of the location of a problematic component and this, combined with the teachings of the other references regarding the criticality of the connections, would have obviously led one of ordinary skill in the art to display the location of those problematic connections to facilitate efficient and effective corrective action.

Conclusion

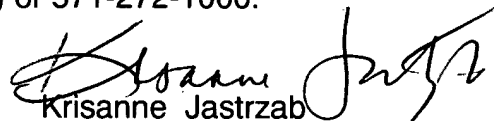
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Thurs. 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Krisanne Jastrzab
Primary Examiner
Art Unit 1744

May 24, 2006